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## **REMARKS**

### **Formal Matters**

Claims 17-36 are pending.

Claims 17-26, 30 and 32 were examined and rejected. The claims are not amended.

Applicants respectfully request reconsideration of the application in view of the remarks made herein.

### **This Response in General**

The Applicants note that this is the *seventh* Office Action issued in this application.

The Applicants submit that the claims have not been significantly amended since the response to the first Office Action.

While the Office's willingness to withdraw rejections is acknowledged and appreciated, the Office is respectfully reminded that examination procedures such as those employed by the Office in this case are not supported by the Office's examination guidelines and, in fact, are inefficient and should be avoided (see MPEP § 707.07(g)<sup>1</sup>).

The Examiner is requested allow the claims without any further delay, after reviewing this response.

### **Request for Interview**

The Applicants request an interview of this case with the Examiner. Exr. Wessendorf is invited to telephone the undersigned, James Keddie, at (650) 833 7723 to arrange the interview.

### **Specification**

The Examiner objects to the specification for allegedly containing new matter.

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<sup>1</sup> MPEP § 707.07(g): Piecemeal examination should be avoided as much as possible. The examiner ordinarily should reject each claim on all valid grounds available, avoiding, however, undue multiplication of references.

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In making this rejection, Examiner objects to the specification being amended to disclose the names of parties to a joint research agreement.

The amendment disclosing the names of parties to a joint research agreement is prescribed by 35 U.S.C. § 103(c)(2)(C)<sup>2</sup> and, as such, is not new matter. Since the law requires this amendment be made in order for the statute to apply, to hold that this amendment is new matter wholly eviscerates Congress' intent behind this law.

Withdrawal of this rejection is requested.

If the Examiner thinks this rejection should be maintained, the Examiner is requested to: a) read 35 U.S.C. § 103(c)(2)(C), which is shown in the footnote below, and b) consult with the Examiner's supervisor, before maintaining this rejection.

**Rejection under 35 U.S.C. § 103 – Uhr and Conneally**

Claims 17-24 and 30 are rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Uhr (U.S. patent 5,612,185) in view of Conneally (Blood, 1996 87:456-64).

In attempting to establish this rejection, the Examiner alleges that Uhr's multiparameter FACS method for identifying tumor cells, in combination with Conneally's retroviral vector system for genetically modifying cells, renders the claims obvious. The Applicants respectfully traverse this rejection.

The Applicants submit that this rejection is deficient for many reasons.

For example, neither reference teaches of a *library* of retroviral vectors encoding different candidate bioactive agents, as required by the instant claims. As such, the combination Uhr and Conneally fails to teach an element of the rejected claims.

This rejection should be withdrawn for this reason alone.

Further, in an attempt to establish this rejection, the Examiner argues that Uhr's antibodies (which bind cell surface markers and label the cells prior to FACS analysis) may be delivered by Conneally's retroviral vector<sup>3</sup>. However, this combination of references is illogical because antibodies

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<sup>2</sup> 35 U.S.C. § 103(c)(2)(C): "the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement."

<sup>3</sup> See, e.g., page 6 of the Office Action: "Uhr does not disclose a retroviral vectors to which the population(library, as claimed) antibodies(bioactive agents, as claimed) are transfected [*sic*]. However, Conneally teaches..... It would have

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produced within a cell would not be expected to bind cell surface markers and label the cells. Thus, one of skill in the art would have no motivation to make this combination of references, and this rejection should be withdrawn.

The Applicants submit that this rejection has been adequately addressed. Withdrawal of this rejection is requested.

**Rejection under 35 U.S.C. § 103 – Nolan in view of Jia-Ping and Uhr**

Claims 17-25, 30 and 32 are rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Nolan (WO 97/27212) in view of Jia-Ping and Uhr. The Applicants respectfully traverse this rejection.

In response to this rejection, the Examiner is respectfully referred to the Applicant's response of July 24, 2006 (which is responsive to the Office Action dated February 24, 2006), in which Nolan was addressed.

Summarizing their prior response, Nolan's publication date (July 31, 1997) predates the earliest priority date of this application (April 17, 1997). As such, Nolan qualifies as prior art only under 35 U.S.C. § 102(a)<sup>4</sup>.

A Declaration under 35 U.S.C. § 1.131 (the "Fisher declaration") was submitted with the Applicants' response of July 24, 2006, in order to obviate a rejection over a near identical combination of references (i.e., Nolan in view of Jai-ping or Ryan). The declaration established invention of the subject matter of the rejected claims prior to the Nolan's publication date.

In view of the foregoing discussion, the Applicants submit that Nolan is disqualified as a prior art reference and cannot preclude the patentability of the instant claims. Thus, this rejection should be withdrawn.

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been obvious to one having ordinary skill in the art at the time of filing the invention was to use a retroviral vectors in the method of Uhr.....".

<sup>4</sup> The PCT application upon which Nolan's publication (WO97/27212) is based was filed on January 23, 1997. Nolan's filing date is *prior to* the November 19, 2000 date of enactment of amended 35 U.S.C. § 102(e). As such, Nolan is not available as prior art as of its filing date, and is not citable as "102(e)-type art".

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With the above in mind, the Applicants note that MPEP §§ 715.02<sup>5</sup> and 715.03<sup>6</sup> explicitly state that a showing of completion of a single species encompassed by a genus claim is sufficient to antedate a reference. As such, according to the MPEP, the Fisher declaration need not show completion of every species within the claimed genus for this rejection to be withdrawn.

To the extent that any further discussion is necessary, the Examiner is referred to the Applicants' response of February 24, 2006.

Withdrawal of this rejection is requested.

**Rejection under 35 U.S.C. § 103 – Nolan in view of Jia-Ping, Uhr and Hide**

Claim 26 is rejected under 35 U.S.C. § 103 as unpatentable over Nolan in view of Jia-Ping, Uhr and Hide. The Applicants respectfully traverse this rejection.

As discussed above, Nolan's publication date is antedated by the Inventor's activities.

As such, Nolan cannot preclude the patentability of the rejected claims, and this rejection should be withdrawn.

**Statutory double patenting**

Claim 26 is rejected under 35 U.S.C. § 101 as allegedly being drawn to the same invention claimed in claim 1 of U.S. patent 6,897,031 (the "031 patent"). This is a statutory-type double patenting rejection. The Applicants respectfully traverse this rejection.

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<sup>5</sup> MPEP § 715.02.I: "applicant's 37 CFR 1.131 affidavit must show possession of ..... something falling within the claim(s) prior to the effective date of the reference being antedated". MPEP § 715.02.II: "a reference or activity applied against generic claims may (in most cases) be antedated as to such claims by an affidavit or declaration under 37 CFR 1.131 showing completion of the invention of only a single species, within the genus, prior to the effective date of the reference or activity....."

<sup>6</sup> MPEP § 715.03.II: "In general, where the reference or activity discloses the claimed genus, a showing of completion of a single species within the genus is sufficient to antedate the reference or activity under 37 CFR 1.131. Ex parte Biesecker, 144 USPQ 129 (Bd. App. 1964)."

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According to MPEP 804.II.A<sup>7</sup>, a statutory-type double patenting rejection requires that an *identical* invention is claimed in two different patent applications. If the claims differ in any material way, then the claims are not identical and thus cannot be rejected under 35 U.S.C. § 101 for statutory-type double patenting.

Claim 26 of the instant case is materially different from claim 1 of the '031 patent. As such, claim 26 of the instant case and claim 1 of the '031 patent are not identical and thus cannot be rejected under 35 U.S.C. § 101 for statutory-type double patenting.

For example, *inter alia*, claim 26 of the instant case requires sorting a population of cells based on at least *five* parameters, whereas claim 1 of the '031 patent requires assaying cells based on at least *three* parameters. Further, claim 26 requires cells comprising a library of retroviral vectors. Such cells are not required in claim 1 of the '031 patent.

In view of the foregoing discussion, the Applicants submit that the invention recited in claim 26 of the instant application is *not identical* to the invention recited in claim 1 of the '031 patent. Thus, in accordance with MPEP 804.II.A, claim 26 of the instant case cannot be rejected for statutory-type double patenting over claim 1 of the '031 patent.

Withdrawal of this rejection is requested.

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<sup>7</sup> MPEP 804.II.A: In determining whether a statutory basis for a double patenting rejection exists, the question to be asked is: Is the same invention being claimed twice? 35 U.S.C. 101 prevents two patents from issuing on the same invention. "Same invention" means identical subject matter. *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1984); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957).

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The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number RIGL-036CIP.

Respectfully submitted,  
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Date: May 23, 2007By: 

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